Major Kidney Clinical Research Studies and Projects Inventory*

National Analgesic Nephropathy Study (NANS)

1. Administrative Data

(a) Name of study/research project and acronym:

National Analgesic Nephropathy Study (NANS)

(b) Type of study/research project (randomized clinical trial, epidemiological study, database, etc.):

Case control study in incident end stage renal disease (ESRD) patients

(c) Funding status (currently funded, study/project completed):

Currently funded

(d) Recruitment status (recruitment completed, currently recruiting):

Complete by 2/10/03

(e) For studies/project currently recruiting: indicate total sample size/ number currently enrolled, anticipated period of recruitment:

Approximately 210 cases and 200 controls

(f) Data coordinating center principal investigator contact information (mailing address, phone, fax, e-mail address):

David W. Kaufman, Sc.D.
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Boston University School of Public Health
1010 Commonwealth Avenue
Boston, MA 02215
Phone: 617-734-6006
Fax: 617-738-5119
E-mail: dkaufman@slone.bu.edu

(g) Number of recruiting sites, list of principal investigators at recruiting sites and contact information as in (f) above:

Wake Forest University, Winston-Salem, NC:

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Professor of Physiology and Internal Medicine
Chief of Nephrology
Wake Forest University School of Medicine
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Winston-Salem, NC 27157-1053
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Dallas Nephrology Associates, Dallas, TX:

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University of North Carolina, Chapel Hill, NC:

William F. Finn, M.D.
Professor of Medicine
University of North Carolina School of Medicine
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Medical College of Ohio, Toledo, OH:

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Chairman, Department of Medicine
Medical College of Ohio
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Toledo, OH 43614
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Fax: 419-383-6244
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(h) List of principal investigators at central laboratories/facilities (identify type of central facility) and contact information as in (f) and (g) above:

Radiology—CT Scan Interpretation:

Richard Clark, M.D.
Professor of Radiology
Vice Chair for Research
University of North Carolina School of Medicine
UNC Hospital, Room 2006 Old Clinic Building
101 Manning Drive
Chapel Hill, NC 27599
Phone: 919-966-4292
Fax: 919-843-8740
VM: 919-966-2814
Pager: 919-216-7098
E-mail: Rclark@med.unc.edu

(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

[EAC members available from Paul Eggers, NIDDK]

(j) Private-sector support (type of support, e.g., financial, donation of drugs/placebo, etc.)

N/A

2. Study Design

(a) Objective:

To learn of the relationship between analgesic use and end stage renal disease; to learn if the non-contrasted CT scan is able to detect a unique entity, analgesic nephropathy (AN).

(b) Study design:

Case control study with detailed questionnaire and CT scan to > 200 incident ESRD patients and questionnaire to > 200 matched non-ESRD controls.

(c) Major inclusion criteria:

Incident ESRD defined by dialysis begun within the previous two months

(d) Major exclusion criteria:

Exclusion Criteria in NANS
Hemodialysis initiated more than 90 days ago
Age < 35 years
Reside outside catchment area of participating clinic
Acute renal failure
Treated Diabetes (unless unrelated to ESRD Progression)
Polycystic kidney disease
Renal transplant failure
Glomerulonephritis (biopsy-proven)
Amyloidosis
Multiple myeloma
Renal artery stenosis (angiographically-proven)
Heredity nephritis
AIDS nephropathy
Acute renal failure that fails to recover
Toxic disease secondary to anti-neoplastic agents
Sickle cell disease
Nephrectomy
Current pregnancy
History of organ transplantation

(e) Description of the intervention(s):

Detailed questionnaire administered by trained staff; non-contrasted abdominal CT scan (patients only)

(f) Baseline/eligibility visit schedule (number of visits, major assessments):

Patients: CT scan and interview within two months of starting dialysis

Controls: in-person interview

(g) Follow-up contact schedule (frequency, type of visit/phone, in-clinic, major assessments):

N/A

(h) Primary outcome, secondary outcomes:

CT findings, development of ESRD related to history of analgesic use; type of use; amount of use

(i) Brief summary of power estimates used to justify sample size/duration, including critical assumptions (i.e., effect-size estimates, estimated event rates or rate of change in outcome measure):

CT criteria for AN in relation to analgesic use: 5% of 200 ESRD patients have positive criteria; power=80%, alpha=5%. Detectable relative risks are 7.5 for analgesic exposure prevalence of 4%; 10 for prevalence of 2%; 14 for prevalence of 1%.

ESRD in general in relation to analgesic use: 190 "non-AN" cases, 200 controls; power=80%, alpha=5%. Detectable relative risks are 3.2 for analgesic exposure prevalence of 4%; 4.4 for prevalence of 2%; 6.6 for prevalence of 1%.

(j) Web site:

N/A

3. Data and Biological Sample Resources

Database will be provided to NIDDK at conclusion of study.

4. Ancillary Studies

None to date

(a) Process and contact person (name, address, phone, fax, and e-mail address) for application to perform ancillary studies:

N/A

(b) List of ancillary studies approved, completed and ongoing (including source of funding and amount):

N/A

5. List of Publications and Presentations (full citations, also note manuscripts in progress)

Clark RL, Buckalew V, Finn Hayes W, W Henrich, Kaufman D, Shapiro J, Warshauer D, Wilber K. Frequency of incidental findings in normal subjects and ESRD patients undergoing CT scans for the National Analgesic Nephropathy Study (NANS). *JASN* 12: A1017, 2001.

Clark R, Buckalew V, Finn W, Henrich W, Kaufman D, Shapiro J, Wilber K. Comparison of methods for renal volume determination using non-contrasted helical CT scans in normal volunteers. *JASN* 12: A1018, 2001.